

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MCNEIL CONSUMER	:	MDL NO. 2190
HEALTHCARE, ET AL., MARKETING	:	
AND SALES PRACTICES LITIGATION	:	
	:	
Applies to:	:	
ALL ACTIONS	:	

MEMORANDUM

McLaughlin, J.

July 14, 2011

This putative class action represents a consolidation of individual cases filed in various courts throughout the United States, which have been transferred to this Court by the Judicial Panel on Multidistrict Litigation. The litigation arises out of purported quality control issues affecting certain over-the-counter healthcare products manufactured by Johnson & Johnson's ("J&J") consumer healthcare division, McNeil Consumer Healthcare ("McNeil").

The plaintiffs allege that J&J and McNeil, along with certain executives and board members (collectively, the "J&J Defendants"), as well as third-party contractors (the "Contractor Defendants"), engaged in a conspiracy to conceal systemic quality control problems and manufacturing defects that began at least as early as 2008, and which affected adult and children's medications, many of which were manufactured at McNeil's facility in Fort Washington, Pennsylvania. As a consequence of this scheme, the plaintiffs allegedly purchased McNeil products at higher prices than they were worth, based on their reliance on

the J&J Defendants' reputation for safe and effective medications. In this action, the plaintiffs seek to recover their out-of-pocket payments for the products in question. The plaintiffs also seek damages for the alleged conspiracy to conceal the quality control problems that first came to light in 2010.

Both the J&J Defendants and the Contractor Defendants have filed motions to dismiss. The Court held oral argument on these motions on June 29, 2011. The Court will grant the motions and will dismiss the plaintiffs' claims in their entirety for lack of standing. The claims against the J&J Defendants will be dismissed without prejudice, and the Court will permit the plaintiffs to amend their complaint. The claims against the Contractor Defendants, however, will be dismissed with prejudice.

I. Facts as Alleged in the Consolidated Amended Complaint¹

As an initial matter, the Court notes that the allegations in the consolidated amended complaint ("CAC") are difficult to distill into a coherent summary. This is largely

¹ In evaluating a motion to dismiss under Rule 12(b)(6), a court must accept all well-pleaded facts as true, and must construe the complaint in the light most favorable to the plaintiff, while disregarding any legal conclusions. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009). The court must then determine whether the facts alleged are sufficient to show that the plaintiff has a "plausible claim for relief." Fowler, 578 F.3d at 210. If the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, then the complaint has alleged, but it has not shown, that the pleader is entitled to relief. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2008).

due to the fact that the plaintiffs' allegations relate to disparate and in some cases unrelated events, each of which implicates different sets of products manufactured by the J&J Defendants.² At no point in the CAC do the plaintiffs identify which particular products they purchased; instead, the plaintiffs use umbrella terms such as "Subject Products" and "Recalled Subject Products." With these issues in mind, the Court has done its best to piece together the plaintiffs' allegations below.

A. Background: April 30, 2010, FDA Report and Recall

The twenty-seven named plaintiffs are individuals from sixteen states plus Ontario, Canada, who bring suit on behalf of themselves and a putative nationwide class³ of consumers who have purchased unspecified "Subject Products" manufactured by McNeil from at least December 2008 to the present.⁴ The plaintiffs

² In addition, the plaintiffs often refer to J&J, McNeil, and the individual defendants interchangeably.

³ The plaintiffs also purport to represent individuals from other countries, which the plaintiffs refer to as "Other Places," and which include Canada, the Dominican Republic, the United Arab Emirates, Fiji, Guam, Guatemala, Jamaica, Puerto Rico, Panama, Trinidad & Tobago, and Kuwait. CAC ¶ 1.

⁴ The plaintiffs refer to all drugs allegedly affected by quality control issues as the "Subject Products." The Subject Products include various forms of the following: Tylenol Infants' Drops, Tylenol Infants' Suspension, Tylenol Suspensions, Tylenol Plus Suspensions, Children's Tylenol Plus, Tylenol Meltaways, Tylenol, Motrin Infants' Drops, Motrin Suspensions, Motrin Cold Suspensions, Junior Strength Motrin, Motrin IB, Zyrtec Liquids in Bottles, Benadryl Allergy Liquids in Bottles, Children's Benadryl Fastmelt Tablets, Benadryl Allergy Tablets, Peppid, Roloids, Mylanta and Alternagel Liquid Products, Simply Sleep, and St. Joseph Aspirin. "Subject Products," Ex. A to CAC.

contend that these Subject Products were defective due to quality control problems in McNeil's manufacturing process. Although the quality control problems began at least as early as 2008, the plaintiffs did not become aware of such problems until April 30, 2010, when the Food and Drug Administration ("FDA") issued a report citing McNeil's Fort Washington facility for various deficiencies in its manufacturing process. CAC ¶¶ 5, 7.

In a report issued on April 30, 2010, the FDA listed twenty separate "observations" that had been made by FDA investigators based on inspections of McNeil's Fort Washington facility between April 19 and April 30, 2010. These observations related to a number of deficiencies in McNeil's manufacturing operations, including failures of production controls to ensure consistency in the strength, quality and purity of products; the use of contaminated raw materials, some of which contained gram-negative organisms; the manufacture of "super-potent batches" of certain products; the presence of foreign materials in some products; and a general lack of cleanliness and record keeping. CAC ¶¶ 195, 202-03; April 30, 2010, FDA Report, Ex. C to CAC.

On the evening of April 30, 2010, following the FDA report, McNeil announced a voluntary recall of a subset of the Subject Products identified above. The recall covered approximately forty types of children's and infants' products manufactured at the Fort Washington plant, and encompassed over 136 million bottles of products in total. The recall was issued only as to products bearing certain National Drug Codes,

production dates and lot numbers. Throughout the CAC, the plaintiffs refer to the subset of Subject Products that were recalled on, and subsequent to, April 30, 2010, as the "Recalled Subject Products."⁵ CAC ¶¶ 7, 9.

In the wake of the recall announcement, McNeil shut down its manufacturing operations at the Fort Washington facility. In addition, the recall announcement triggered a congressional investigation that led to two hearings before Congress in 2010. CAC ¶¶ 7-9, 169-71, 173.

The plaintiffs allege that the J&J Defendants' recall was inadequate for multiple reasons, and has therefore not fully compensated the putative class members. First, although all of the Subjects Products identified in the CAC suffered from "serious problems," the J&J Defendants only recalled a subset of those products, which are identified in the CAC as the Recalled Subject Products. The plaintiffs have therefore paid inflated prices for defective products that have not been subject to any recall.⁶ CAC ¶¶ 4, 7, 9, 232.

⁵ The "Recalled Subject Products" include various forms of Tylenol Infants' Drops, Children's Tylenol Suspensions, Children's Tylenol Plus Suspensions, Motrin Infants' Drops, Children's Motrin Suspensions, Children's Motrin Cold Suspensions, Children's Zyrtec Liquids in Bottles, and Children's Benadryl Allergy Liquids in Bottles. CAC ¶ 9.

⁶ Based on the CAC and the representations made by plaintiffs' counsel at oral argument, it appears that the broader category of "Subject Products" includes products manufactured at additional locations apart from McNeil's Fort Washington facility.

Even with respect to the products that were subject to the April 30, 2010, recall (the Recalled Subject Products), the accompanying refund offer was substantively deficient and has not fully compensated the plaintiffs for several reasons. First, the recall announcement was deliberately delayed until the evening of Friday, April 30, 2010, so as to avoid substantial media attention. As a consequence, only a small portion of consumers who purchased the Recalled Subject Products have learned about the recall, and an even smaller number have availed themselves of the refund offer. CAC ¶¶ 7-8.

Even those consumers who availed themselves of the refund offer were not adequately compensated. In the early stages, McNeil encouraged consumers to take "high value coupons" for future McNeil products instead of cash refunds. The coupons, however, have no present cash value, are not transferable, and are "worthless" because the McNeil Fort Washington plant has closed. The plaintiffs aver that "[s]ome members of the consumer Class in this case received such worthless coupons." CAC ¶ 16. The J&J Defendants later began offering consumers a "limited opportunity" to request a partial cash refund of their out-of-pocket payments. Both the coupons and cash refunds, however, were only offered to consumers who could satisfy the J&J Defendants' eligibility criteria. CAC ¶¶ 14-15, 18.

In particular, to receive a cash refund or a coupon, consumers had to complete a web-based form that required the consumer to enter the specific product name, as well as its

National Drug Code number, lot number and expiration date. The refund webpage contained no provisions for consumers who did not retain the product bottle, notwithstanding the J&J Defendants' instructions to discard products subject to the recall.⁷ Therefore, consumers who used up or discarded the products cannot receive a coupon or cash refund. CAC ¶¶ 225-29, 233.

Apart from these general allegations, the CAC does not aver that any named plaintiff attempted to avail himself of the refund offer and was not made whole. Instead, the plaintiffs rely on the experiences of non-plaintiff third-party consumers to illustrate specific examples of the refund offer's deficiencies. In particular, the plaintiffs cite to comments posted by consumers on an internet blog maintained by the J&J Defendants as part of the refund offer.⁸ For example, a man named Evan D. Owen criticized the J&J Defendants for delaying the recall announcement until late in the evening on Friday, April 30. Mr. Owen also complained that the operators handling the customer

⁷ The J&J Defendants encouraged consumers, as a "precautionary measure," not to administer unused Recalled Subject Drugs to children, and instead to dispose of said products by mixing them with materials such as kitten litter or coffee grounds and placing the products in a sealed bag. CAC ¶ 13.

⁸ The plaintiffs' allegations regarding third-party consumers are derived from 98 pages of documents relating to the refund offer that the J&J Defendants furnished to the plaintiffs after an initial status conference before the Court on December 13, 2010. The 98 pages largely consisted of printouts from the J&J Defendants' websites. None of the third-party consumers are named plaintiffs in this action. See CAC ¶¶ 234-35; Pls.' Opp'n to Defs.' Mot. to Dismiss ("Pls.' Opp'n"), at 9.

service lines were difficult to reach, and those who could be reached were "data collectors and coupon issuers." The plaintiffs aver that Mr. Owen's experience emphasizes the fact that the J&J Defendants were pushing coupons over cash refunds.⁹ CAC ¶¶ 235-39.

In addition, the plaintiffs cite to a blog poster named "Aaron L." to show that cash refunds, when offered, were inadequate. Aaron L. commented that he was having "issues" with the amount of his cash refund, based on the fact that he had "to destroy 6 various McNeil products and received a check for \$10.00." CAC ¶ 241. The plaintiffs also append to their complaint a document dated May 13, 2010, signed by Peter Luther, McNeil's President, that was issued to healthcare providers. In the document, Mr. Luther explained that cash refunds were calculated based on the "average retail price" of the product in question. According to the plaintiffs, the average retail price did not include any applicable taxes. In addition, average retail prices have been inconsistent between internal McNeil documents. Therefore, any consumer who receives the average retail price is not made whole. CAC ¶¶ 58, 242-43.

⁹ The plaintiffs also cite to a document entitled "Recall Update: Change to Compensation Policy," an internal J&J document that directed customer service representatives, "[e]ffective immediately," to offer a check first and then a coupon. According to the plaintiffs, this only would have been necessary if the J&J Defendants had previously been pushing coupons instead of cash. CAC ¶ 244.

In view of the foregoing allegations, the plaintiffs contend that the refund offer has failed to compensate them. The plaintiffs also allege that the quality control problems that first came to light on April 30, 2010, and that prompted the recall, had been ongoing at J&J and McNeil since at least 2008. These quality control issues, which affected at a minimum all Subject Products, were concealed as part of a conspiracy to avoid disclosure. The 2010 recall and the accompanying refund offer, which have failed to compensate consumers, are symptomatic of this scheme to conceal the truth and to minimize the consequences of the J&J Defendants' actions. The Court will turn to the conspiracy allegations below.

B. Conspiracy Allegations

The plaintiffs' conspiracy allegations relate to events that largely occurred prior to the April 30, 2010, FDA report and the subsequent recall of children's and infants' medications. Taken together, the plaintiffs argue that these allegations reveal systemic quality control problems that were intentionally concealed by the defendants.

1. Violations of State and Federal Laws

The plaintiffs devote many allegations of the CAC to violations of state and federal laws by J&J and its various non-McNeil subsidiaries in recent years. The plaintiffs contend that these violations, which in several cases resulted in the imposition of criminal or civil fines, should have put the J&J

Defendants on "heightened alert" for the conduct giving rise to this action. In brief, the plaintiffs' allegations relate to "kickback" arrangements, as well as schemes to promote the off-label use of prescription drugs.¹⁰

The J&J Defendants argue in their motion to dismiss that these allegations are extraneous and should be stricken under Federal Rule of Civil Procedure 12(f) as immaterial and impertinent to the present action. The Court agrees that these allegations are irrelevant to the present suit, because they do not pertain to quality control problems in general, or the products at issue in this suit in particular. In addition, none of the allegations relate to McNeil Consumer Healthcare. The Court will therefore not go into additional detail with respect to these allegations. See CAC ¶¶ 93-120.

2. Prior Quality Control Problems at J&J and McNeil

The plaintiffs allege that J&J and McNeil's quality control has deteriorated since 2002, largely as a consequence of internal management decisions. Starting in 2002, McNeil began to lay off its experienced quality control staff and replace them with inexperienced contract workers. In 2007, William C. Weldon, the Chairman and CEO of J&J, made significant cuts to J&J's

¹⁰ The plaintiffs reference the following: (1) a kickback scheme between J&J and Omnicare covering certain prescription drugs; (2) a kickback scheme involving DePuy hip and knee replacement products; (3) a \$6.15 million fine assessed against non-McNeil J&J subsidiaries for lack of transparency and/or product misbranding; and (4) the off-label promotion of Topamax, Risperdal, and Nactrecor prescription drugs. CAC ¶¶ 93-120.

Corporate Compliance Group, which was charged with conducting "tough audits" and overseeing quality control at all of the J&J companies. In the same year, McNeil issued an internal memorandum that reflected its ongoing quality control problems, including a high percentage of operator errors in every work center. CAC ¶¶ 129, 136-37.

J&J and McNeil's quality control was also subject to FDA criticism on multiple occasions prior to April 30, 2010. In 2004, for instance, the FDA cited McNeil for bad sampling and poor record keeping. On January 11, 2006, the FDA issued an "Enforcement Report" citing problems with several of the same products that were again cited in the 2010 report.¹¹ For example, in the 2006 report, the FDA identified particulate matter in Children's Motrin Bubblegum Suspensions. This same observation appeared again in the 2010 report. Similarly, the 2006 report identified the presence of foreign substances in the Bubblegum and Cherry Blast Flavors of Tylenol Oral Suspensions. These two products were again cited in the 2010 report. Finally, the 2006 report identified Berry Flavor Children's Motrin Oral Suspension as being "sub-potent." In contrast, several products were cited in the 2010 report for being "super-potent." CAC ¶¶ 206-09.

¹¹ Several of the issues that were cited in the 2006 report had led the FDA to initiate a recall of certain products in 2005, before the report was released. CAC ¶¶ 207-09.

The FDA has conducted a number of additional inspections at McNeil's facilities in both Fort Washington and Lancaster, Pennsylvania, and has found deficiencies with regard to McNeil's laboratory controls, equipment cleaning processes, and its investigations of identified problems.¹² In January 2010, the FDA issued McNeil a warning letter expressing concerns about McNeil's quality control and its failure to investigate quality problems. CAC ¶¶ 194-96.

3. J&J and McNeil Product Recalls

The plaintiffs allege that the J&J Defendants' quality control problems, as outlined above, have led to a number of product recalls. The manner in which the defendants have handled the recalls, in turn, evidences a conspiracy to conceal quality control problems. The plaintiffs focus in particular on a so-called "phantom recall" of Motrin IB and a subsequent public recall in July 2009.

The plaintiffs allege that in August 2008, McNeil distributed over 88,000 packages of defective Motrin IB. Three months later, McNeil discovered a dissolution problem with the drug, and sometime thereafter hired third-party contractors to perform a clandestine, or "phantom," recall. Pursuant to this "phantom recall," McNeil hired third-party contractors Inmar,

¹² In February 2008 and June 2009, the FDA issued reports citing McNeil's Fort Washington facility for inadequate investigations and for mishandling complaints. CAC ¶¶ 139-40.

Inc.¹³, and WIS International,¹⁴ and instructed them to visit various retailers, act like normal customers, and purchase all of the Motrin IB off of the shelves. J&J's specific instructions to the third-party contractors were as follows:

[Q]uickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave . . . THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!

CAC ¶¶ 145-50.¹⁵

The plaintiffs allege that McNeil subsequently misrepresented to the FDA that the third-party contractors were simply performing an audit in order to determine whether McNeil should initiate a formal recall. However, the FDA ultimately received a copy of the internal memo containing the instructions to the third-party contractors and confronted McNeil. Finally, on July 9, 2009, McNeil publicly recalled the affected Motrin IB.

¹³ The plaintiffs also allege that Inmar's subsidiaries, Carolina Supply Chain Services, LLC ("CSCS"), and Carolina Logistics Services, LLC ("CLS"), participated in the "phantom recall." CAC ¶¶ 64-65.

¹⁴ The plaintiffs allege that Inmar, Inc. hired WIS International as a subcontractor to assist with the "phantom recall." See CAC ¶ 66.

¹⁵ The plaintiffs do not allege a precise date when the "phantom recall" occurred, but instead imply in the CAC that the "phantom recall" occurred approximately eight months prior to the public recall. See CAC ¶ 153. At oral argument, however, the plaintiffs clarified that the "phantom recall" was part of a process that occurred over the course of several months, beginning with a "market assessment" in May 2009, and ending with the removal of products from shelves sometime thereafter. See Tr. of Oral Arg. on June 29, 2011 ("Tr."), at 96-97. The Contractor Defendants, by contrast, contend that the "phantom recall" occurred in June 2009, a point which the plaintiffs have not disputed. See Contractor Defs.' Mot. at 5; Tr. at 16, 94.

The "phantom recall" was ultimately a subject of the two hearings held before Congress in 2010. CAC ¶¶ 151-54.

The plaintiffs cite to additional recalls involving McNeil products spanning from the "phantom recall" in 2008 to a recall in December 2010. These recalls included, among others, a September 2009 recall of Tylenol products that had been contaminated with gram-negative bacteria. Prior to initiating the September 2009 recall, McNeil allegedly engaged third-party contractor Inmar, Inc., to conduct a "market assessment" to determine how much of the product remained on store shelves in July 2009. CAC ¶¶ 155-59.

In November and December of 2009, McNeil also recalled certain Tylenol pills manufactured at its Las Piedrad, Puerto Rico facility. McNeil had received reports of musty, moldy odors emanating from said pills as early as 2008, but did not investigate for over a year. This recall was later expanded to other products, including Benadryl, Motrin, Roloids, and other lots of Tylenol, in January, June, and July of 2010.¹⁶ CAC ¶¶ 160-66.

¹⁶ The J&J Defendants recalled additional products after the April 30, 2010 recall. These recalls include: (1) an October 2010 recall of Tylenol caplets manufactured at McNeil's Fort Washington plant, due to musty odors; (2) a November 2010 recall of Benadryl tablets and Motrin caplets because of uncharacteristic consistencies and manufacturing problems; and (3) a December 2010 recall of Mylanta and AlternaGel liquid antacid because alcohol was not disclosed as an active ingredient on the packaging. CAC ¶¶ 184-91.

4. Allegations Regarding Individual Defendants

The plaintiffs allege that certain individuals employed as executives and board members at J&J and McNeil were integrally involved in this conspiracy to conceal quality control issues.

For instance, the plaintiffs allege that William C. Weldon, the Chairman and CEO of J&J, had personal knowledge of the conditions at J&J's manufacturing facilities, including the Fort Washington facility. In addition, Mr. Weldon was "integrally involved in and responsible for" the decisions that led to deteriorating quality control at J&J. CAC ¶ 55. Apart from these general averments, the plaintiffs offer three specific allegations about Mr. Weldon. First, Mr. Weldon made significant cuts to J&J's "corporate compliance group" in 2007. Second, in the wake of several recalls in 2010, Mr. Weldon announced: "This is not a systemic problem at J&J." CAC ¶ 141. Approximately one week after this announcement, however, J&J issued two additional recalls. Finally, when testifying before Congress on September 30, 2010, Mr. Weldon admitted that McNeil had secretly performed a "phantom recall" of defective Motrin products, and admitted "McNeil should have handled things differently." Mr. Weldon also acknowledged that J&J had let the public down by not maintaining high quality standards, and accepted full responsibility. CAC ¶¶ 137, 141-42, 222-23.

The plaintiffs make the same general allegations of personal knowledge and involvement regarding Colleen Goggins, the former Worldwide Chairman of the J&J Consumer Health Segment, and

Peter Luther, the President of McNeil. Apart from the general allegations noted above, the plaintiffs also aver that Colleen Goggins testified before Congress on May 27, 2010, and admitted that J&J and McNeil had "not lived up to [their] responsibility" in light of the April 30, 2010, recall. Ms. Goggins allegedly tried to minimize the severity of the recall, however, by claiming that there were no health risks related to the use of the recalled products. CAC ¶¶ 215-17.

With respect to Mr. Luther, the plaintiffs aver that the FDA met with senior J&J and McNeil officials on February 19, 2010, to discuss their concerns regarding J&J and McNeil's conduct. Mr. Luther was allegedly present at this meeting, and was therefore put on notice of the FDA's concerns. At the meeting, the FDA specifically raised its concerns about quality control issues, and the J&J Defendants' failure to report material information to the FDA in a timely manner. CAC ¶¶ 196, 198-200.

The plaintiffs also assert the same general allegations of personal knowledge and integral involvement against Rosemary Crane, a former Company Group Chairman at J&J, as well as Mary Sue Coleman, Ph.D.; Michael M.E. Johns, M.D.; Susan L. Lindquist, Ph.D.; and David Satcher, M.D., Ph.D., each of whom serves or served on the Board of Directors of J&J. No specific allegations regarding any of these defendants appear in the CAC. CAC ¶¶ 57, 59-62.

C. Claims Asserted in the CAC

Based on the foregoing allegations, the plaintiffs claim that they have paid inflated prices for McNeil products and have not been fully compensated. The plaintiffs do not claim that they suffered any physical injury; instead, their claims are based entirely on economic injuries. The allegations of specific economic injury pertaining to the named plaintiffs, however, are sparse. The plaintiffs do not allege which particular Subject Products or Recalled Subject Products they purchased. The plaintiffs also do not allege that they availed themselves of any refund offers, and were inadequately compensated thereby. Instead, the CAC sets forth identical allegations with respect to each of the twenty-seven named plaintiffs, as follows:

[Name] is an individual and resident of [state] who, during the relevant time period, purchased a number of Subject Products, including some Recalled Subject Products. As a result, [Name], like other members of the Class (and/or possible Sub-Class of [State] consumers only), suffered damages from the unlawful scheme and conspiracy, and the concealment of the same by Defendants, which damages result from his out of pocket payments for Subject Products which were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines. [Name] has not been reimbursed fully for his out-of-pocket payments for Subject Products.

CAC ¶¶ 28-52.

The plaintiffs have named as defendants McNeil and J&J, as well as individual defendants William C. Weldon, Colleen Goggins, Rosemary Crane, Peter Luther, Mary Sue Coleman, Michael M.E. Johns, Susan L. Lindquist, and David Satcher (collectively,

the "J&J Defendants"). The plaintiffs have also named as defendants the entities alleged to have performed "market assessments" and the "phantom recall": Inmar, Inc. and its subsidiaries, Carolina Supply Chain Services, LLC ("CSCS"), Carolina Logistics Services, LLC ("CLS"), as well as WIS International (collectively, the "Contractor Defendants").

Against all defendants, the plaintiffs assert claims for: violations of the consumer fraud laws of sixteen states (Count I);¹⁷ violations of RICO (Count II); violations of the Magnuson-Moss Warranty Act (Count III); Negligence (Count VII); Negligent Misrepresentation/Fraud (Count VIII); Conspiracy, Concert of Action and Aiding and Abetting (Count IX); Unjust Enrichment (Count X); and Declaratory Relief (Count XI). Against the J&J Defendants, the plaintiffs also assert claims for Strict Products Liability - Manufacturing Defect (Count IV); Strict Products Liability - Failure to Warn (Count V); and Breach of Implied Warranties (Count VI).

II. Procedural Background

This action represents a consolidation of individual cases filed in various courts throughout the country. On May 12, 2010, the case Haviland v. McNeil Consumer Healthcare, Civil No. 10-2195, was filed in this Court, asserting economic injuries

¹⁷ The named plaintiffs represent a total of sixteen different states. If this case proceeds, the plaintiffs also intend to assert claims under all fifty states' consumer fraud laws.

against J&J and McNeil in light of the April 30, 2010, recall. Eight additional cases, also arising out of the April 30, 2010, recall, were filed in other courts, including the Northern District of Illinois and the Central District of California.¹⁸ Each case asserted claims for economic injury only, with the exception of Rivera v. Johnson & Johnson, which also asserted claims for physical injury. On October 8, 2010, the Judicial Panel on Multidistrict Litigation transferred the above-referenced cases to this Court, where they and all future "tag-alongs" were consolidated into an MDL. Since that time, two "tag-along" cases have been transferred to this Court.¹⁹

The Court held an initial status conference with counsel on December 13, 2010. A consolidated amended complaint was filed on January 12, 2011, which named as additional defendants the Contractor Defendants. The plaintiffs also widened the scope of their claims to include events both before

¹⁸ Those cases include: Roberson v. McNeil Consumer Healthcare, Civil No. 10-5560 (N.D. Ill.); Rivera v. Johnson & Johnson, Civil No. 10-5579 (C.D. Cal.); Nguyen v. McNeil Consumer Healthcare, Civil No. 10-5580 (N.D. Ill.); Michaud v. McNeil Consumer Healthcare, Civil No. 10-5587 (N.D. Ill.); Smith v. McNeil Consumer Healthcare, Civil No. 10-5654 (N.D. Ill.); Burrell v. McNeil Consumer Healthcare, Civil No. 10-5656 (N.D. Ill.); and DeGroot v. McNeil Consumer Healthcare, Civil No. 10-5657 (N.D. Ill.).

¹⁹ Specifically, Coleman v. McNeil Consumer Healthcare, Civil No. 10-6905 (S.D. Ohio) and Harvey v. Johnson & Johnson, Civil No. 11-2363 (E.D. Mo), were transferred to this Court. The CAC also added additional plaintiffs not included in the above cases.

and after the April 30, 2010, recall.²⁰ Both groups of defendants filed motions to dismiss the CAC in its entirety on April 1, 2011. The plaintiffs filed an omnibus opposition on May 13, 2011. Both groups of defendants filed reply briefs on June 9, 2011. The Court held oral argument on June 29, 2011. The Court will now grant the motions to dismiss.

III. Analysis of the Motions to Dismiss

As a threshold matter, both groups of defendants argue that the named plaintiffs lack standing under Article III of the United States Constitution, and all of their claims must therefore be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1).²¹

Specifically, the defendants argue that the named plaintiffs lack standing because they have not established any injury-in-fact. Although the plaintiffs allege in a conclusory fashion that they have not been fully reimbursed for their out-of-pocket expenses for the products in question, they do not allege what specific harm that they have suffered. With respect to the broad category of Subject Products, for instance, the plaintiffs allege only that the products suffered from "serious problems." The plaintiffs do not aver specifically what those

²⁰ All claims for physical injury were omitted from the CAC. The plaintiffs seek damages for economic injury only.

²¹ The defendants have also moved to dismiss the CAC on other grounds, including failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).

problems were or how they were injured therefrom. As for the subset of products that were recalled after the April 30, 2010, FDA report (the Recalled Subject Products), the plaintiffs identify only hypothetical deficiencies with the refund offer, based on the experiences of non-plaintiffs. The defendants argue that there are no allegations that any named plaintiff attempted to but was unable to obtain a refund, or received a refund that was otherwise inadequate.

The Contractor Defendants additionally argue that the plaintiffs lack standing because they cannot show that the Contractor Defendants' conduct caused any injury to the plaintiffs. In particular, the Contractor Defendants are not alleged to have manufactured, distributed or promoted any Subject Products. Instead, the only allegations with respect to the Contractor Defendants are that they participated in the removal of Motrin IB from store shelves. According to the Contractor Defendants, the plaintiffs have not shown how this conduct led to any economic injuries.

The Court will begin its analysis with the threshold issue of Article III standing.

A. Article III Standing

The doctrine of standing derives from Article III of the United States Constitution, which limits the jurisdiction of federal courts to "Cases" and "Controversies." U.S. Const. art. III, § 2. The "irreducible constitutional minimum" of standing

requires that a plaintiff establish three elements in order to invoke federal jurisdiction. First, the plaintiff must have suffered an injury-in-fact, which is an invasion of a legally protected interest that is (a) concrete and particularized, and (b) actual or imminent. Second, the plaintiff must establish a causal connection between the injury and the conduct complained of. Third, the plaintiff must establish that it is likely, as opposed to merely speculative, that the injury will be "redressed by a favorable decision." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (U.S. 1992) (citations omitted).

Standing is ordinarily a threshold issue for any case. To that end, "a plaintiff must allege a distinct and palpable injury to himself, even if it is an injury shared by a large class of other possible litigants." Warth v. Seldin, 422 U.S. 490, 501 (1975). The requirement that a named plaintiff have standing applies equally in the context of class actions. Therefore, "even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." Lewis v. Casey, 518 U.S. 343, 357 (1996). If no named plaintiffs establish standing, none may seek relief on behalf of other members of the class. O'Shea v. Littleton, 414 U.S. 488, 494 (1974).²²

²² A plaintiff must also establish standing on a claim-by-claim basis. Allen v. Wright, 468 U.S. 737, 752 (1984). The

The Court will begin by addressing the injury-in-fact prong, which constitutes the main dispute in this action. The Court will then turn to the causation prong, which the Contractor Defendants contend has not been satisfied. Neither group of defendants has addressed the third element of redressability.

1. Injury-in-Fact

An injury-in-fact must be "distinct and palpable," not "abstract or conjectural or hypothetical." Danvers Motor Co., Inc. v. Ford Motor Co., 432 F.3d 286, 291 (3d Cir. 2005) (citations omitted). The injury must be particularized, which means that the injury must affect the plaintiff "in a personal and individual way." Lujan, 504 U.S. at 561 n.1. This requirement ensures that a litigant has a personal stake in the litigation. Danvers Motor Co., 432 F.3d at 291. Although injury-in-fact cannot be reduced to a simple formula, economic injury is a "paradigmatic" form of injury-in-fact, and a claim for damages generally supports standing. Id.

In addition, the injury-in-fact requirement is "very generous," requiring only that a plaintiff allege "some specific, 'identifiable trifle' of injury." Danvers Motor Co., 432 F.3d at 294 (citations omitted). To survive a motion to dismiss for lack

Court need not conduct a claim-by-claim standing analysis at this time, however, because it concludes that the same pleading deficiencies plague each of the plaintiffs' claims. See Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 139 n.5 (3d Cir. 2009).

of standing, therefore, the plaintiffs must plead that they suffered some concrete form of harm. Id. at 292.

For purposes of this memorandum, the Court will analyze separately the broader category of Subject Products and the narrower category of Recalled Subject Products. This analytical structure corresponds with the allegations in the CAC, which distinguish between Subject Products and Recalled Subject Products and offer different factual averments with respect to each category.

a. Subject Products

The Court concludes that the plaintiffs have not established injury-in-fact with respect to the Subject Products, because the CAC does not permit the Court to discern what, if any, harm the named plaintiffs have suffered. As an initial matter, the CAC is deficient insofar as the plaintiffs do not allege which particular products they purchased. Instead, each named plaintiff alleges that he or she "purchased Subject Products including some Recalled Subject Products." CAC ¶¶ 28-52. The Subject Products category, in turn, encompasses, "at a minimum," a list containing twenty-one different products, and at least seventy-four types of said products. At no point in the CAC do the plaintiffs identify a single product that they purchased from this large and indefinite list.

In addition, the plaintiffs do not allege how the unspecified Subject Products they purchased were defective.²³ Instead, the plaintiffs allege only that each Subject Product suffered from "serious problems." CAC ¶ 4. The "serious problems" are not elaborated upon, and could therefore reference any of the allegations in the CAC that the Court described in Part I of this memorandum. For instance, it is possible that the serious problems include the dissolution issues that affected certain lots of Motrin IB, which prompted a "phantom recall" and a subsequent public recall in July 2009. It is also possible that the serious problems include the numerous FDA warnings and recalls to which the plaintiffs cite in the CAC, or simply the general allegations of deteriorating quality control at J&J. Notably, several of the products that appear on the "Subject Products" list are not even alleged to have been recalled or subject to any FDA citations. Because the plaintiffs do not identify which products were purchased, it is impossible to match the many incidents outlined in the CAC with the specific drugs that fall under the Subject Products category.

Even assuming that the "serious problems" identified above encompass the allegations of specific product recalls and FDA citations, the plaintiffs fail to allege any personal harm arising therefrom. This deficiency follows from the plaintiffs'

²³ As noted, the Court will analyze separately the subset of Subject Products that were recalled after the April 30, 2010, FDA report (the Recalled Subject Products).

failure to allege which particular products they purchased. For instance, the plaintiffs make numerous allegations about the "phantom recall" and the subsequent public recall of Motrin IB. The plaintiffs do not, however, allege that they purchased the affected lots of Motrin IB and were not made whole. The same logic applies to all of the remaining allegations in the CAC: the plaintiffs cite to approximately eleven recalls apart from the April 30, 2010, recall, and a handful of FDA reports, but do not allege how they were harmed by any of these incidents. Instead, the plaintiffs only allege, in general terms, that they "suffered damage" as a result of their "out of pocket payments for Subject Products" that were unsafe and not as represented, and that they have "not been reimbursed fully" for their out-of-pocket payments. CAC ¶¶ 28-52.

In view of these deficiencies, the Court concludes that the plaintiffs have not established injury-in-fact with respect to claims involving the Subject Products. Even if the Court were to read the allegations of "serious problems" generously, and assume that the plaintiffs have identified problems affecting certain Subject Products, the plaintiffs have not alleged that they, rather than non-plaintiff members of the class, have suffered injury as a result of said problems. Under Supreme Court case law, named plaintiffs must establish that they themselves have suffered injury. See Lewis v. Casey, 518 U.S. 343, 357 (1996). In the absence of particularized harm, the plaintiffs' injuries are abstract and hypothetical, rather than

distinct and palpable. See Danvers Motor Co., 432 F.3d at 291. Conclusory allegations that the plaintiffs have "not been reimbursed" are insufficient to show an invasion of a legally protected interest. See id. at 290-91.

The Court's analysis is consistent with the case law cited by the parties. For instance, the defendants cite to Rivera v. Wyeth-Ayerst Laboratories, 283 F.3d 315 (5th Cir. 2002). In Rivera, the Fifth Circuit dismissed the claims of a putative class action brought against Wyeth, which sought damages for economic injuries arising out of a defective drug that caused liver failure in some patients. The Fifth Circuit concluded that the named plaintiffs had not established injury-in-fact, because the plaintiffs had failed to allege that the drugs were somehow defective as to them, or otherwise caused them specific injury. The plaintiffs' conclusory allegations of "economic injury" were never defined or elaborated upon. The Fifth Circuit explained that the plaintiffs could not prevail by establishing that Wyeth violated a legal duty owed to other consumers; instead, the injury must be personal. Rivera, 283 F.3d at 319-20.

Similarly, the defendants cite to Whitson v. Bumbo, 2009 U.S. Dist. LEXIS 32282 (N.D. Cal. Apr. 15, 2009). In Whitson, the plaintiff brought a putative class action for economic injuries arising out of defective baby seats, which had caused injuries to non-plaintiff children. The plaintiff asserted economic injury based on an overpayment theory, as in the present case. The Whitson court concluded that the plaintiff

lacked Article III standing, because she had not alleged that her own product manifested any defect or that she had suffered any specific injury. Instead, the only allegations of injury were "entirely conclusory statements" that the plaintiff "did not receive the benefit of [her] bargain," without elaboration as to how. The Whitson court held that the plaintiff could not rely on the injuries of non-parties to establish standing. Whitson, 2009 U.S. Dist. LEXIS at *15-18 & n.4.

These cases are consistent with the Court's reasoning in the present action. As in Rivera and Whitson, the plaintiffs in this case have not alleged that the Subject Products were defective as to them, or that the plaintiffs were otherwise injured. The plaintiffs assert in conclusory terms that they suffered out-of-pocket expenses and were not made whole, but do not make any specific allegations as to how. Therefore, their allegations of injury are based on harm that occurred to non-plaintiff third parties.

Finally, the plaintiffs were unable to cure their deficient allegations either in their opposition brief or at oral argument. The plaintiffs devote the majority of their opposition to arguing that they have standing with respect to the Recalled Subject Products. With respect to the broader category of Subject Products, which were afflicted by "serious problems," the plaintiffs echo the allegations from the CAC and contend that the products were "filthy, adulterated, contaminated and sub-

standard." Pls.' Opp'n at 5. On this basis, the plaintiffs argue:

Plaintiffs' allegations of purchase of the J&J Defendants' "Subject Products" alone are sufficient to prove that they have suffered an injury in fact. Plaintiffs and the Class suffered actual economic loss via out-of-pocket payments for Subject Products which were not of the same quality and condition as represented at the time of sale and some of which were unsafe.

Pls.' Opp'n at 15. As discussed above, such conclusory allegations cannot establish injury-in-fact. The Court will therefore dismiss the claims pertaining to the Subject Products for lack of standing.

b. Recalled Subject Products

The plaintiffs' allegations are somewhat more detailed with respect to the Recalled Subject Products. In contrast to the general allegations of "serious problems" pertaining to the Subject Products, the plaintiffs allege tangible defects affecting the Recalled Subject Products. Specifically, the plaintiffs allege that all Recalled Subject Products manifested a defect in at least one of two respects: (1) they suffered from the problems identified in the April 30, 2010, FDA report; and/or (2) consumers were urged to stop using and dispose of the products as part of the recall announcement, thereby rendering the products useless. In addition, the plaintiffs allege specific deficiencies in the J&J Defendants' refund offer in an attempt to establish injury.

Notwithstanding these allegations, the Court concludes that the plaintiffs have failed to establish injury-in-fact with respect to the Recalled Subject Products. Although the Third Circuit has described the injury-in-fact requirement as "very generous," a plaintiff must still allege some form of specific injury, even if small, in order to survive a motion to dismiss for lack of standing. See Danvers Motor Co., 432 F.3d at 292, 294. The plaintiffs do not meet this burden. First, as with the Subject Products, the plaintiffs do not identify which products they purchased, and instead allege that they "purchased Subject Products including some Recalled Subject Products." CAC ¶¶ 28-52. More fundamentally, however, the plaintiffs do not allege individualized injuries, but instead rely entirely on injuries suffered by non-plaintiff class members.

In order to establish injury, the plaintiffs allege a number of deficiencies in the J&J Defendants' refund offer. As described at length in Part I of this memorandum, the plaintiffs aver that: (1) the recall announcement was delayed, so as to minimize consumer awareness; (2) the J&J Defendants pushed "worthless" coupons over cash refunds; (3) consumers were required to furnish difficult-to-obtain information in order to obtain refunds, notwithstanding the J&J Defendants' instructions to dispose of unused products; and (4) cash refunds, when received, were inadequate and did not cover applicable taxes or disposal costs. As a consequence, the plaintiffs were not fully compensated for the Recalled Subject Products.

Further, in order to particularize these general allegations, the plaintiffs cite to the experiences of various non-plaintiff consumers. Two such individuals posted comments on the J&J Defendants' recall blog. As described above, a non-plaintiff named Evan D. Owen expressed his frustration both that the J&J Defendants delayed their recall announcement until the evening, and that the telephone lines were operated by "coupon issuers." A man named "Aaron L," by contrast, complained about the amount of his cash refund.

The plaintiffs also make several allegations with respect to unidentified class members. With regard to the "worthless" coupons, the plaintiffs allege that "[s]ome members of the Consumer class in this case received such worthless coupons." CAC ¶ 16. In addition, with respect to the cash refunds, the plaintiffs allege that "[s]uch refunds were not offered to all consumers in the Class." Id. ¶ 18.

None of these allegations are particularized to the named plaintiffs. For instance, although the plaintiffs allege that the recall announcement was delayed, no named plaintiff alleges that he or she was unaware of the recall as a consequence. Similarly, the plaintiffs allege that the defendants pushed "worthless" coupons over cash, but no named plaintiff alleges that he or she has received such a coupon; instead, the CAC alleges that "[s]ome members of the Consumer class" did. The same pleading deficiencies plague the allegations regarding cash refunds. The plaintiffs allege that

cash refunds were contingent on strict eligibility criteria and did not fully compensate consumers for taxes and disposal costs. No named plaintiff, however, alleges that he or she attempted to obtain a cash refund, and was either denied a refund or received a refund that was inadequate.

The plaintiffs have also failed to inject greater specificity into their allegations by way of their opposition brief or oral argument. Instead, the plaintiffs have repeated the same allegations that appear in the CAC.²⁴ Apart from general arguments about "class members," the only particular individuals whom the plaintiffs referenced in their opposition brief or at oral argument are the same two non-plaintiff consumers who posted on the J&J Defendants' recall blog. As a consequence, the plaintiffs have failed to establish that a single named plaintiff suffered any of the many injuries identified by the plaintiffs.²⁵

²⁴ In summary, the plaintiffs devote several pages to arguing that the recall announcement was deliberately delayed; that the J&J Defendants pushed coupons over cash; and that the criteria for obtaining coupons or cash refunds were vague and undefined. Pls.' Opp'n at 7-11.

²⁵ On this point, the parties dispute the applicability of In re Ford Motor Company Ignition Switch Products Liability Litigation, 2001 WL 1266317 (D.N.J. Sept. 30, 1997). In Ford Motor, the plaintiffs owned vehicles that were subject to a recall due to a potentially defective ignition switch. The plaintiffs, whose own vehicles had not manifested the defect, sued for economic damages. The Court dismissed the claims of those particular plaintiffs, noting that they had failed to allege any injury that might require compensation apart from the defendants' offer to replace the ignition switches. Ford Motor, 2011 WL at *5. To the extent that Ford Motor is relevant to this case, it is consistent with the Court's analysis. Ford Motor is

The plaintiffs also argue that the mere purchase of the Recalled Subject Products, in and of itself, is sufficient to establish injury-in-fact. Specifically, the plaintiffs contend that their economic losses arose at the moment the J&J Defendants recalled the products in question and advised consumers not to use them. In support of this argument, the plaintiffs rely on American Federation of State County and Municipal Employees v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., 2010 WL 891150 (E.D. Pa. Mar. 11, 2010). In American Federation, the issue was whether plaintiffs had standing based on their purchase of fentanyl patches, all of which were recalled and had to be disposed of, but only some of which manifested the defect in question. Id. at *3. The Court concluded that the plaintiffs, who were health and welfare trust funds that had purchased the fentanyl patches for their members, had standing regardless of whether the defect manifested itself. The plaintiffs had standing because they "paid or will pay expenses related to the purchase of and reimbursement of ... fentanyl patches that had to be discarded." Id. at *4. The plaintiffs argue that in this case, they too "have paid or will pay expenses related to the purchase and replacement of Recalled Subject Products." Pls.' Opp'n at 18.

illustrative of the requirement that plaintiffs allege some form of particularized injury. As in Ford Motor, the plaintiffs in this case have failed to show how they were inadequately compensated, either by the J&J Defendants' refund offer or otherwise.

The Court finds American Federation to be distinguishable from the present case. A reading of the case reveals that the claims in American Federation were based on more particularized allegations of harm than exist here. First, the plaintiffs were able to identify the precise products they had purchased: fentanyl patches in specific dosages. Second, the plaintiffs were able to identify the precise harm they had suffered or would suffer: reimbursement and repurchase expenses for the patches that were procured for members, and which had to be discarded. Third and finally, it does not appear that any refund program was established in American Federation by which the plaintiffs could have been made whole.

In the present case, by contrast, the plaintiffs do not identify which products they purchased, nor do they allege the precise manner in which they have been harmed. No plaintiff has alleged, for instance, that he has paid or will pay costs to replace a product that had to be discarded. Finally, no plaintiff alleges that any harm arising from the recall was not, or could not be, adequately resolved by the refund offer.²⁶

²⁶ The fact that the defendants offered a refund may not, in and of itself, defeat standing. Nonetheless, the plaintiffs must still show that the remedy offered by the defendants was somehow inadequate as to them. The plaintiffs' own case law makes this clear. See, e.g., In re Mattel, Inc. Toy Lead Paint Prods. Liab. Litig., 588 F. Supp. 2d 1111, 1116 (C.D. Cal. 2008) (holding plaintiffs' claims were not preempted by defendants' voluntary product replacement program, provided plaintiffs could "prove that the voluntary remedy offered by the defendant was inadequate").

Additional cases cited by the defendants further undermine the plaintiffs' argument that the purchase of Recalled Subject Products alone establishes injury-in-fact. Specifically, these cases emphasize the importance of each named plaintiff's particular circumstances to the standing inquiry. For instance, several courts have held that individuals who consume defective products cannot sue for economic damages unless the products failed to work as intended. In the Rivera case discussed above, for example, the Fifth Circuit held that those plaintiffs who had consumed an allegedly defective drug could not establish economic injury, because the plaintiffs had not alleged that the products had been ineffective as to them; therefore, they received the benefit of the bargain. Rivera, 283 F.3d at 320.

Similarly, in Myers-Armstrong v. Actavis Totowa, LLC, 2009 WL 1082026 (N.D. Cal. April 22, 2009), a plaintiff sued for economic damages after consuming a product that was recalled due to contamination in the manufacturing process. The Myers-Armstrong court concluded that the plaintiff lacked standing because she had consumed the pills and obtained their benefit with no downside. The plaintiff was therefore in a different position from a consumer who had purchased but not consumed the defective product. Myers-Armstrong, 2009 WL at *4.

Rivera and Myers-Armstrong are not binding on this Court. Nonetheless, these cases illustrate the weaknesses in the plaintiffs' argument. Specifically, the cases reveal that plaintiffs who have purchased Recalled Subject Products are not

in a monolithic category. Instead, it is possible that the plaintiffs who purchased Recalled Subject Products could have, for instance: (1) consumed the products and received the benefit of the bargain; (2) disposed of the products and failed to avail themselves of the refund offer; (3) disposed of the products and obtained an inadequate refund; or (4) disposed of the products and were made whole. Any of these scenarios is plausible based on the vague allegations of the CAC, and each would result in a different standing analysis. The mere purchase of Recalled Subject Products, therefore, cannot be sufficient to establish injury-in-fact.

In view of the plaintiffs' failure to establish injury-in-fact, the Court will dismiss their claims for lack of standing.²⁷ The dismissal will be without prejudice as to the claims against the J&J Defendants.²⁸ All claims against the

²⁷ Because the Court will dismiss the CAC for lack of standing, it need not address the defendants' other bases for dismissal.

²⁸ Although the Court will dismiss the claims against the J&J Defendants without prejudice, the Court notes that it considered dismissing with prejudice all claims against the individuals who serve or served on J&J's Board of Directors. The CAC is devoid of any specific allegations regarding these individuals. Indeed, apart from being named as defendants, these individuals are never again mentioned in the CAC. At oral argument, plaintiffs' counsel was unable to provide additional information regarding the director defendants. Tr. at 98-100. Out of an abundance of caution, the Court will permit the plaintiffs to amend their allegations against the director defendants. The Court alerts counsel, however, that it considers the claims to be dismissible, and will likely reach the same conclusion if the director defendants are named in the amended complaint, absent more specific allegations.

Contractor Defendants will be dismissed with prejudice, however, because the Court concludes that the plaintiffs are unable to establish the second requirement of standing, causation. The Court turns to the causation requirement below.

2. Causation

In addition to injury-in-fact, Article III standing requires a causal relationship between the injury and the conduct complained of. Winer Family Trust v. Queen, 503 F.3d 319, 325 (3d Cir. 2007) (citations omitted). To satisfy this causation requirement, the plaintiffs must establish that the injuries in question "fairly can be traced to the challenged action" of a particular defendant, rather than to the action of an independent third party. Whitmore v. Arkansas, 495 U.S. 149, 155 (1990); Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 137-38 (3d Cir. 2009). This requirement is not as demanding as the proximate causation required under tort law. Instead, an indirect causal relationship may suffice, so long as there is a "substantial likelihood" that the defendant's conduct caused the plaintiffs' harm. Pub. Interest Research Grp. v. Powell Duffryn Terminals, 913 F.2d 64, 72 (3d Cir. 1990).

The Court also expects more specific allegations regarding the executive defendants, Mr. Weldon, Ms. Goggins, Ms. Crane, and Mr. Luther. Although the CAC contains some specific allegations regarding these defendants, they are sparse. At oral argument, plaintiffs' counsel explained that the plaintiffs could provide additional information upon amendment. Tr. at 99-101. The Court expects to see such allegations if the executives are named as defendants in the amended complaint.

The Contractor Defendants argue that the plaintiffs cannot establish the requisite causation between their putative injuries and the particular actions of the Contractor Defendants.²⁹ Specifically, the sole allegations regarding the Contractor Defendants pertain to the market assessment and "phantom recall" of Motrin IB in 2009. According to the Contractor Defendants, the plaintiffs have failed to show how this "phantom recall" was causally related to the sweeping injuries alleged in the CAC.

By contrast, the plaintiffs argue that the Contractor Defendants caused the injuries in question because, by conducting a "phantom recall," the Contractor Defendants helped the J&J Defendants to "unlawfully conceal[] the fact that the Subject Products ... were substandard and defective." Pls.' Opp'n at 21. This fraudulent concealment, in turn, caused injury to consumers who continued to pay inflated prices for defective Motrin IB. Id. In addition, had the Contractor Defendants not participated in the "phantom recall," the J&J Defendants "would have been forced to publicly disclose the defective nature of their Subject Products and would have issued a broader recall." Id. at 23.

The Court agrees that the plaintiffs have failed to establish causation. Assuming, *arguendo*, that certain named plaintiffs purchased the affected lots of Motrin IB, for purposes of the causation inquiry, such plaintiffs could have been injured

²⁹ The J&J Defendants have not raised the issue of causation.

at two different times: (1) prior to the "phantom recall"; or (2) during and after the "phantom recall," insofar as certain defective lots of Motrin IB were not captured by the recall and remained on store shelves.

With respect to those plaintiffs who purchased Motrin IB prior to the "phantom recall," there are no allegations that the Contractor Defendants had any pre-existing relationship with the J&J Defendants or the products in question. The Contractor Defendants are not alleged to have participated in the manufacture, distribution, or marketing of the defective Motrin IB. Instead, based on the CAC, the Contractor Defendants first became involved with the J&J Defendants when they were engaged to conduct the "phantom recall" of Motrin IB. It follows, therefore, that any injuries that occurred prior to the "phantom recall" cannot be "fairly traced" to the Contractor Defendants' conduct. See Toll Bros., 555 F.3d at 137-38.

The plaintiffs have also failed to establish causation with respect to any named plaintiffs who purchased affected Motrin IB during or after the "phantom recall." The plaintiffs rely on a theory of "but for" causation, and contend that the J&J Defendants would have been forced to conduct an earlier and more complete public recall, but for the Contractor Defendants' participation in the "phantom recall." This argument, however, finds no support in the CAC.

First, there are no allegations that the Contractor Defendants participated in, or had influence over, the decision

to conduct a "phantom recall," or decisions regarding the scope of said recall. Second, the plaintiffs have not alleged that the Contractor Defendants had any knowledge of the specific defects affecting Motrin IB, such that they would have or should have refused to conduct a "phantom recall." Finally, even if the Contractor Defendants had refused to conduct a "phantom recall," there is no basis for assuming that the J&J Defendants would have been unable to find other contractors to conduct the recall, or that the J&J Defendants otherwise would have foregone a "phantom recall" in favor of a public recall. The plaintiffs' theory of causation, therefore, hinges on the Contractor Defendants' possessing a degree of influence over the J&J Defendants that is not plausible based on the limited allegations in the CAC. Instead, the plaintiffs' injuries appear to be based on conduct more appropriately attributed to the J&J Defendants alone.

Focusing on the specific conduct attributable to the Contractor Defendants, the Court is left with allegations that the Contractor Defendants removed allegedly defective Motrin IB from store shelves. It is not clear how the plaintiffs could have been harmed by the removal of products that they contend were defective. Instead, each purportedly defective unit of Motrin IB that was removed from store shelves became unavailable for purchase by a consumer. It does not logically follow that the plaintiffs could have been injured by these actions.

The causal relationship is even more tenuous with respect to Subject Products apart from Motrin IB. The plaintiffs rely on the same theory of "but for" causation, contending that:

"but for" Contractor Defendants' actions in coordinating with J&J Defendants to remove only select Subject Products from select retail outlets, J&J would have been forced to make a full-blown, public recall and to properly inform consumers that their Subject Products were unsafe and defective.

Pls.' Opp'n at 22. Once again, this argument is unsupported by any allegations in the CAC. The plaintiffs have alleged no connection between the Contractor Defendants and any of the Subject Products. As was the case with Motrin IB, the plaintiffs have not alleged that the Contractor Defendants were responsible for the production, distribution, or marketing of the Subject Products. Furthermore, the plaintiffs have not alleged that the 2009 "phantom recall" involved any products apart from Motrin IB. It is therefore unclear how the Contractor Defendants' participation in the "phantom recall" could have influenced the J&J Defendants' decisions with respect to other Subject Products.³⁰

³⁰ The plaintiffs append to their opposition brief a series of email communications involving WIS International, and ask that the Court take judicial notice thereof. In the emails, WIS employees discuss the possibility of performing a "potentially larger recall" for J&J in July 2009 involving Children's Tylenol. The WIS personnel also stated that WIS and Inmar would be performing a market assessment to determine the quantities of Tylenol remaining on store shelves. See June 30, 2009, Emails Attached to Congressional Letter, App. A to Pls.' Opp'n. These emails do not affect the Court's analysis. First, the plaintiffs have been unable to show, in the CAC, their opposition brief, or at oral argument, that an additional "phantom recall" ever took

The plaintiffs' case law also fails to support their argument. The plaintiffs cite to Bennett v. Spear, 520 U.S. 154 (1997), in support of their "but for" theory of causation. In Bennett, the Fish and Wildlife Service (the "Service") issued an advisory "biological opinion," recommending that a federal bureau implement certain changes to avoid jeopardizing endangered species. The plaintiffs, who claimed injury based on these recommendations, brought suit against the Service after the bureau stated its intent to comply. The Supreme Court concluded that the plaintiffs' injuries were "fairly traceable" to the Service, because the Service's advisory opinion exerted a "powerful coercive effect" on the bureau that was "virtually determinative"; furthermore, the changes likely would not have been made absent the opinion. Bennett, 520 U.S. at 169-71. The plaintiffs contend that the Contractor Defendants exerted a similar coercive effect over the J&J Defendants in this case.

The Court disagrees that Bennett is applicable to this case, because the plaintiffs have failed to show that the Contractor Defendants exerted any influence over the J&J Defendants. In contrast, it appears that the J&J Defendants provided all direction to the Contractor Defendants with respect

place. Furthermore, there is no plausible connection between a "market assessment" and the plaintiffs' purported injuries. The plaintiffs do not define the term "market assessment," or explain in any fashion how the Contractor Defendants, as part of this market assessment, could have influenced the J&J Defendants with respect to recall decisions.

to their limited conduct. In the absence of any coercive relationship, Bennett cannot support the plaintiffs' claims.

Based on the foregoing, the Court concludes that the plaintiffs have failed to establish that their purported injuries are "fairly traceable" to the Contractor Defendants' conduct. The Court will therefore dismiss all claims against the Contractor Defendants for lack of standing. The dismissal will be with prejudice, because the Court concludes that the plaintiffs would be unable to establish causation upon amendment.

Specifically, at oral argument, the plaintiffs were unable to articulate any additional allegations that could be made against the Contractor Defendants. Although the plaintiffs expressed their belief that the scope of the Contractor Defendants' conduct extended beyond the "phantom recall," they lacked information in support of this claim. Tr. 36-37. Instead, the plaintiffs repeated allegations from the CAC that the Contractor Defendants undertook a second market assessment involving Children's Tylenol sometime around July 2009, after the "phantom recall" of Motrin IB.³¹ The plaintiffs suspect that, as part of this market assessment, the Contractor Defendants made certain recommendations to the J&J Defendants regarding whether to recall Children's Tylenol. The J&J Defendants, in turn, waited to recall the product until April 30, 2010, presumably on

³¹ See CAC ¶¶ 155-59. As noted above, the plaintiffs also attached as Exhibit A to their opposition brief a series of email communications from WIS employees discussing a market assessment with respect to Children's Tylenol.

the basis of these recommendations. Tr. 39-41; 60-61. According to the plaintiffs, this reveals the Contractor Defendants' participation in the J&J Defendants' scheme.

At oral argument, the plaintiffs were unable to provide any factual basis for the above-described argument. Instead, plaintiffs' counsel conceded that the plaintiffs had "very limited information," but expected to obtain additional information to support their arguments in the course of discovery. Tr. 60-61. The Court cannot permit amendment on this basis. Under the applicable pleading standards, the Court is required to assess factual allegations as they appear on the face of the complaint, not based on how claims might be shaped by the course of discovery. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007). To that end, the allegations in the CAC, and as elaborated upon at oral argument, cannot plausibly establish causation. In view of the Court's conclusion that the plaintiffs cannot cure these deficiencies with amendment, the Court will dismiss all claims against the Contractor Defendants with prejudice.

The Court's decision to dismiss the claims against the Contractor Defendants with prejudice is reinforced by the plaintiffs' failure to satisfy the Federal Rule 12(b)(6) pleading standard, as set forth in Twombly and Iqbal. As described above, the CAC contains few allegations regarding the Contractor Defendants' specific conduct. Notwithstanding these limited allegations, the plaintiffs assert eight substantive causes of

action against the Contractor Defendants, based on sweeping and indefinite claims of injury. In the majority of the plaintiffs' substantive claims, however, the CAC fails to distinguish between the J&J and Contractor Defendants, instead lumping both groups together under the term "defendants."

As a consequence of the plaintiffs' failure to distinguish among defendants, it is nearly impossible for the Court to discern the factual underpinning of each claim. Indeed, several claims are facially inapplicable to the Contractor Defendants. For instance, the plaintiffs assert a negligence claim against the Contractor Defendants, contending that "[d]efendants owed Plaintiffs a duty to exercise reasonable care in the designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling" of the Subject Products.³² CAC ¶ 502. Nowhere have the plaintiffs alleged, however, that the Contractor Defendants were engaged in any of these enumerated activities.

In addition, many of the plaintiffs' substantive claims are based on allegations of misrepresentations or omissions.³³

³² The Contractor Defendants purportedly breached this duty by: (1) failing to use due care in performing the above activities; (2) failing to provide adequate warnings on product labels and packaging; (3) failing to incorporate reasonable safeguards into the manufacture and design of the products; and (4) failing to investigate complaints. CAC ¶ 504.

³³ For instance, the plaintiffs assert nearly identical allegations with respect to each of their claims under state consumer fraud statutes, based on "[d]efendants' untrue, deceptive, and misleading misrepresentations and non-disclosure of material facts relating to the safety, efficacy and cost

Nowhere in the CAC, however, do the plaintiffs identify any statements made by the Contractor Defendants that could constitute misrepresentations. Instead, the plaintiffs group together all defendants, contending, for instance, that the "[d]efendants made representations that the Subject Products contained the ingredients, concentrations, components, quality and condition as is identified on the label and/or packaging that accompanied the Subject Products." CAC ¶ 512. These claims are deficient insofar as the plaintiffs have not alleged that the Contractor Defendants made, or were in a position to make, any such representations.

Several of the plaintiffs' claims, such as common law fraud, can also be satisfied based on allegations of fraudulent omissions, rather than misrepresentations. Such claims, however, generally require plaintiffs to allege, among other elements, a duty to disclose.³⁴ In this case, the plaintiffs have failed to allege that the Contractor Defendants owed any duty of disclosure towards the plaintiffs.

effectiveness of the Subject Products." See, e.g., CAC ¶ 273. The plaintiffs make similar allegations in connection with their common law fraud and negligent misrepresentation claims. See CAC ¶¶ 508-19.

³⁴ The Court does not attempt to undertake a state-by-state survey to determine the applicable causes of action at this time. Instead, the Court notes for purposes of this discussion that a sample of the state laws at issue in this case require a duty of disclosure in the context of fraudulent omissions. See, e.g., Bermuda Container Line Ltd. v. Int'l Longshoremen's Ass'n, 192 F.3d 250 (2d Cir. 1999); Goodman v. Kennedy, 18 Cal. 3d 335 (Cal. 1976).

To the extent that several of the plaintiffs' substantive claims are subject to heightened pleading under Rule 9(b), these pleading deficiencies become more acute.³⁵ The Court of Appeals for the Third Circuit has held that Rule 9(b) requires plaintiffs to allege "the who, what, when, where, and how" of the events at issue. In re Rockefeller Ctr. Props. Sec. Litig., 311 F.3d 198 (3d Cir. 2002). The conclusory allegations identified above, which often refer to the Contractor Defendants interchangeably with the J&J Defendants, lack the requisite specificity to satisfy this heightened pleading standard.

Finally, the plaintiffs' RICO claim against the Contractor Defendants is independently dismissible because the plaintiffs cannot establish continuity of the alleged racketeering activity. RICO's continuity requirement is both a "closed and open-ended concept, referring either to a closed period of repeated conduct, or to past conduct that by its nature projects into the future with a threat of repetition." H.J. Inc. v. Northwestern Bell Tel. Co., 492 U.S. 229, 241 (1989). Closed-ended continuity exists when the series of predicate acts extends over a substantial period of time. Id. at 242. Open-ended continuity might be present where, even though the predicate acts are close in time, the acts themselves pose a specific threat of

³⁵ The parties dispute the application of Rule 9(b) to the allegations in the CAC, particularly in connection with claims brought under state consumer fraud statutes. There is no dispute, however, that at a minimum, Rule 9(b) applies to the plaintiffs' RICO and common law fraud claims.

indefinite repetition or are part of an ongoing entity's regular way of doing business. Id. at 242-43.

The alleged offenses involving the Contractor Defendants conceivably spanned from early 2009 to around July 2009. Specifically, the Contractor Defendants were engaged by the J&J Defendants sometime in early 2009 to perform a market assessment and "phantom recall" of Motrin IB. At the latest, this "phantom recall" was completed by June 2009. The plaintiffs allege that the second market assessment, which involved Children's Tylenol, occurred in July 2009. CAC ¶ 157. At most, therefore, the plaintiffs have alleged conduct spanning over the course of several months, which is insufficient to establish closed-ended continuity. See Hughes v. Consol-Pennsylvania Coal Co., 945 F.2d 594, 611 (3d Cir. 1991) (holding that twelve months is not sufficient to establish a closed-ended scheme). As the Court has already concluded, the plaintiffs cannot establish a connection between these discrete events and the J&J Defendants' subsequent product recalls.

Further, there is nothing about these acts that involves an inherent threat of repetition or any indication that the alleged offenses are a regular way of doing business for the Contractor Defendants. Instead, the allegations suggest that the Contractor Defendants' work was a short-term project that came to an end. As a consequence, the plaintiffs have not established open-ended continuity, and therefore their RICO claim is not cognizable. See H.J. Inc., 492 U.S. at 242-43.

IV. Conclusion

For the foregoing reasons, the Court will dismiss the CAC in its entirety for lack of standing. The dismissal will be without prejudice as to the claims against the J&J Defendants, and the Court will permit the plaintiffs to file an amended complaint within thirty days of this Memorandum and Order. The claims against the Contractor Defendants, however, will be dismissed with prejudice.

An appropriate order shall issue separately.